Graham Medical Technologies LLC (dba GraMedica)
Traditional 510(k) Premarket Submission
OsteoWedge™ Opening Wedge Bone Locking System

JUL - 6 2011

Section 5 – 510(k) Summary

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FDA Establishment Registration #: 3004993707

Date Prepared
June 30, 2011

Trade Name
OsteoWedge™ Opening Wedge Bone Locking System

Classification Name
Plate, Bone, Fixation

Regulation Number
888.3030

Product Code
HRS

Classification Panel
Orthopedic

Graham Medical Technologies LLC (dba GraMedica)
Traditional 510(k) Premarket Submission
OsteoWedge™ Opening Wedge Bone Locking System

Device Class
Class 2

Device Description
The OsteoWedge™ Open Wedge Bone Locking Plate System consists of plates and screws and incorporates a screw-to-plate locking mechanism. The plate is attached to a prepared surface of the involved bone(s) of the foot using six (6) screws for fixation. The plates are available in six (6) wedge sizes. The fully threaded screws are available in 2 diameters, with numerous lengths.

Intended Use
The OsteoWedge™ Opening Wedge Bone Locking Plate System is used for adult and transitional adolescent (18 to 21 years old) patients for the purpose of stabilization and/or correction of angular deviations within an individual bone or in between two adjacent bones in the foot, such as opening wedge osteotomy for first metatarsal cuneiform joint deviations.

Predicate Device(s)
1. Arthrex, Inc., Low Profile Plate and Screw System
2. Darco International, Inc., DACRO Locking Bone Plate System

The following table identifies and compares OsteoWedge™ Opening Wedge Bone Locking Plate System to the predicate devices with respect to 510(k) number, product code, regulation number, regulation name and indications for use.

Comparison Table

Manufacturer	**Graham Medical Technologies LLC (dba GraMedica)**	**Darco International, Inc.**	**Arthrex, Inc.**	**OsteoWedge Comparison to Predicates**
Trade Name	OsteoWedge™ Opening Wedge Bone Locking Plate System	DARCO Locking Bone Plate System	Low Profile Plate and Screw System	
510(k) Number	TBD	K061808	K052614	NA
Product Code	HRS	HRS	HRS	Same
Regulation Number	880.3030	880.3030	880.3030	Same
Regulation Name	Single/multiple component metallic bone fixation appliances and accessories	Single/multiple component metallic bone fixation appliances and accessories	Single/multiple component metallic bone fixation appliances and accessories	Same
Indications for use:	The OsteoWedge™ Opening Wedge Bone Locking Plate System is used for adult and transitional adolescent (18 to 21 years old) patients for the purpose of stabilization and/or correction of angular deviations within an individual	The DARCO Locking Bone Plate System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and	The Arthrex Low Profile Plate and Screw System is intended to be used for internal bone fixation of bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies of Hallux Valgus.	Same patient population. Same use – for fixation & stabilization. OsteoWedge is indicated for use only in bones of foot such as the first metatarsal and

Manufacturer	Graham Medical Technologies LLC (dba GraMedica)	Darco International, Inc.	Arthrex, Inc.	OsteoWedge Comparison to Predicates
Trade Name	OsteoWedge™ Opening Wedge Bone Locking Plate System	DARCO Locking Bone Plate System	Low Profile Plate and Screw System	
	bone or in between two adjacent bones in the foot, such as opening wedge osteotomy for first metatarsal cuneiform joint deviations.	toes. The system can be used in both adult and pediatric patients.		first metatarsal cuneiform joints.

Predicate Device Comparison

The OsteoWedge™ Opening Wedge Bone Locking Plate System has been compared with the Low Profile Plate and Screw System and the Locking Bone Plate System. All devices are made of the same materials, provided non sterile for cleaning and sterilization prior to use, have same indications for stabilization and fixation, and are of similar size. The OsteoWedge™ Opening Wedge Bone Locking Plate System has slightly larger 'wedge size' and therefore has narrower 'indications for use' than that of the above predicate device, as described in above Comparison Table.

Summary of Non-Clinical Data Submitted

The following testing has been performed to support substantial equivalence:

Bend Testing, including Static Four Point Bending & Dynamic Four Point Bending Bending Strength
Torsion Testing, Self-Tapping Performance, Axial Pullout Testing, and Insertion and Removal Testing
Cleaning and Sterilization Testing

Summary of Clinical Data Submitted

Clinical trial or testing was not required for the OsteoWedge™ Opening Wedge Bone Locking Plate System. Refer to the non-clinical testing listing above to support substantial equivalence.

Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the OsteoWedge™ Opening Wedge Bone Locking Plate System and the predicate devices do not raise any questions regarding its safety and effectiveness. The OsteoWedge™ Opening Wedge Bone Locking Plate System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Graham Medical Technologies, LLC
% Emergo Group, Inc.
% Ms. Julie Powell
611 West 5th Street, 3rd Floor
Austin, Texas 78701

JUL - 6 2011

Re: K111326
Trade/Device Name: OsteoWedge Opening Wedge Bone Locking System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: April 26, 2011
Received: May 11, 2011

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K111326

Device Name

OsteoWedge™ Opening Wedge Bone Locking Plate System

Indications for Use

The OsteoWedge™ Opening Wedge Bone Locking Plate System is used for adult and transitional adolescent (18 to 21 years old) patients for the purpose of stabilization and/or correction of angular deviations within an individual bone or in between two adjacent bones in the foot, such as opening wedge osteotomy for first metatarsal cuneiform joint deviations.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111326